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ic data: EP 0930082 (A2)

Espacenet

implantable access port

Publication date:	1999-07-21
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Classification:	**- international:** ***A61M39/02;*** (IPC1-7): A61M39/02 **- European:** A61M39/02B
Application number:	EP19990101038 19920827
Priority number(s):	EP19920307797 19920827; US19910753179 19910829; US19920922534 19920729
Also published as:	• EP 0930082 (A3) • EP 0930082 (B1)
Cited documents:	EP0343910 (A2) WO9014118 (A1) US4892518 (A) EP0366814 (A1) View all

Abstract of EP 0930082 (A2)

An implantable access port is capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a dual lumen catheter, said access port comprising. (a) a needle-impenetrable base having a flat floor and walls normal to and upstanding therefrom, said walls defining a first fluid cavity and a second fluid cavity. (b) a septum support configured to mate with the free ends of said walls of said base opposite from said floor thereof, said septum support having formed therethrough a first septum receiving aperture positioned opposite said first fluid cavity when said septum support mates with said free ends of said walls of said base an a second septum receiving aperture positioned opposite said second fluid cavity when said septum support mates with said free ends of said walls of said base; and (c) a needle-impenetrable cap configures to receive said septum support and said base, said cap comprising a top wall having formed therein: (i) a first septum access aperture communicating through said top wall of said cap at a position opposite said first septum receiving aperture when said septum support is received in said cap, said first septum access aperture and said first septum receiving aperture together defining a first access aperture communicating with said first fluid cavity, and (ii) a second septum access aperture communicating through said top wall of said cap at a position opposite said second septum receiving aperture when said septum support is received in said cap, said second septum access aperture and said second septum receiving aperture together defining a second access aperture communicating with said

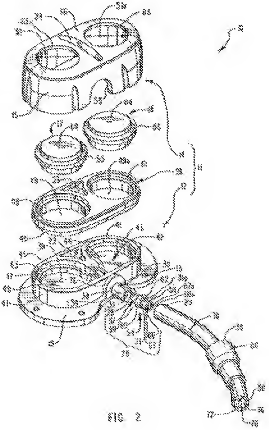

FIG. 2

second fluid cavity, (d) a first needle-penetrable septum captured between said septum support and said cap sealing said first access aperture, and (e) a second needle-penetrable septum captured between said septum support and said cap sealing said second access aperture

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 930 082 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
21.07.1999 Bulletin 1999/29

(51) Int. Cl.[6]: A61M 39/02

(21) Application number: 99101038.0

(22) Date of filing: 27.08.1992

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: 29.08.1991 US 753179
29.07.1992 US 922534

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
92307797.8 / 0 537 892

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Remarks:
This application was filed on 21 - 01 - 1999 as a divisional application to the application mentioned under INID code 62.

(54) Implantable access port

(57) An implantable access port is capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a dual lumen catheter, said access port comprising:

(a) a needle-impenetrable base having a flat floor and walls normal to and upstanding therefrom, said walls defining a first fluid cavity and a second fluid cavity;
(b) a septum support configured to mate with the free ends of said walls of said base opposite from said floor thereof, said septum support having formed therethrough a first septum receiving aperture positioned opposite said first fluid cavity when said septum support mates with said free ends of said walls of said base an a second septum receiving aperture positioned opposite said second fluid cavity when said septum support mates with said free ends of said walls of said base; and
(c) a needle-impenetrable cap configures to receive said septum support and said base, said cap comprising a top wall having formed therein:

(i) a first septum access aperture communicating through said top wall of said cap at a position opposite said first septum receiving aperture when said septum support is received in said cap, said first septum access aperture and said first septum receiving aperture together defining a first access aperture communicating with said first fluid cavity; and
(ii) a second septum access aperture communicating through said top wall of said cap at a position opposite said second septum receiving aperture when said septum support is received in said cap, said second septum access aperture and said second septum receiving aperture together defining a second access aperture communicating with said second fluid cavity;

(d) a first needle-penetrable septum captured between said septum support and said cap sealing said first access aperture; and
(e) a second needle-penetrable septum captured between said septum support and said cap sealing said second access aperture.

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2.16.7/3.6

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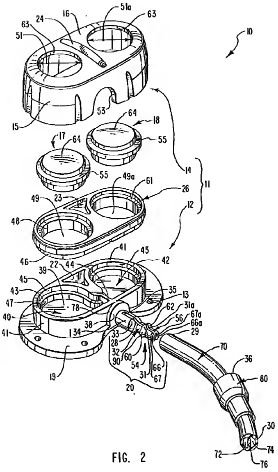
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FIG. 2

Description

BACKGROUND

1. The Field of the Invention

[0001] The present invention relates to a subcutaneously implantable access port. More specifically, the present invention relates to an access port having a plurality of needle-penetrable, self-sealing septums, each affording repeated access to a corresponding plurality of distinct fluid cavities each in communication with a plural lumen catheter.

2. Background Art

[0002] A variety of implantable devices, known as subcutaneous access ports, are utilized to deliver fluids to or to withdraw fluids from the bloodstream of a patient.

[0003] Such access ports typically include a needle-impenetrable housing which encloses one or more fluid cavities and defines for each such fluid cavity an access aperture communicating through the housing on the side thereof which is adjacent to the skin of the patient when the access port is implanted in the body thereof.

[0004] A needle-penetrable septum is received in and seals each access aperture. Exit passageways located in an outlet stem communicate with each of the fluid cavities for dispensing medication therefrom to a predetermined location in the body of the patient through an implanted catheter attached to the access port.

[0005] Once the access port and the catheter have been implanted beneath the skin of a patient, quantities of medication or blood may be dispensed from one such fluid cavity by means of a non-coring needle passed through the skin of the patient and penetrating the septum into one of the respective fluid cavities. This medication is directed in the distal end of the catheter to an entry point into the venous system of the body of the patient.

[0006] Blood may also be withdrawn for sampling from the body of a patient through such an access port. This is accomplished by piercing the skin of the patient and one of the respective septums with a non-coring needle and applying negative pressure thereto. This causes blood to be drawn through the catheter into the fluid cavity corresponding to the pierced septum and then out of the body of the patient through the needle.

[0007] To prevent clotting thereafter, the withdrawal route is flushed with a saline solution or heparin using again a non-coring needle piercing the skin of the patient and the septum in the same manner as if a medication were being infused.

[0008] Both intermittent and continual injections of medication may be dispensed by the access port. Continual access involves the use of a non-coring needle attached to an ambulatory-type pump or a gravity feed IV bag suspended above the patient. The ambulatory-type pump or the IV bag continually feeds the medication or fluid through the needle to the fluid cavity in the access port and from there through the catheter to the entry point into the venous system.

[0009] To facilitate locating each respective septum once the access port has been implanted, some access ports incorporate a raised circular ring located about the entire outer perimeter of the septum. This raised ring enhances the tactile sensation afforded by the subcutaneous septum to the palpating fingertip of a medical practitioner.

[0010] One problem encountered with the use of a raised ring, however, is that tissue located within the area encircled by the ring does not receive a sufficient quantity of blood. This lack of adequate blood flow may lead to necrosis of the encircled tissue. Necrosis adversely affects the localized tissues, and interferes with the passage of a needle therethrough, as well as destabilizing the pocket in which the access port is implanted.

[0011] A related problem arises as a physician attempts to access the septum during use. While a physician may tactually locate the septum through the use of such a raised ring, the natural tendency to avoid missing the septum with the needle causes most physicians to direct the needle through the septum at a point near the raised ring. While the useful life of the self-sealing septum is usually over one thousand penetrations, this assumes that the penetration will be randomly distributed over the surface of the septum. In concentrating the needle punctures near the perimeter of the septum next to the raised ring, the useful life of the septum is dramatically reduced.

[0012] Although the raised ring allows a physician to determine the location of the septum by touch, the portion of the septum that can be positively identified is usually only the perimeter of the rubberized septum, which is typically circular. As a result, the location of one septum does not in any way indicate in which direction the second septum is located.

[0013] In this situation, the doctor has the problem after locating one of the septums, to determine the location of the second septum. If the doctor can identify the perimeter of the first septum, the doctor knows that the second septum is positioned somewhere in a circular path around the first septum. It becomes necessary to probe around this circular path in order to locate the position of the second septum by virtue of the second raised circular ring. Doctors have experienced difficulty in this process, particularly when the implantable device has been in position for a long period of time. While a doctor feels about for the septums, the very process of locating the septums impedes access to the septums, since the fingers of the doctor are covering one or both of the septums.

[0014] To preclude reaction with the tissues in the body of a patient, access ports are constructed of nonreactive materials, such as titanium or stainless steel.

Although these materials are non-reactive, access ports constructed utilizing titanium or stainless steel materials produce an interfering or blurred image of the body of the patient in the vicinity of the implanted access port when diagnostic imaging techniques such as magnetic resonance imaging (hereinafter "MRI") , CAT scans, or computerized tomography are used. The blurred region caused by the presence of a metallic access port in the body of a patient extends beyond the access port itself. Therefore, the use of metallic access ports limits the diagnostic imaging techniques that may be used relative to those areas of the body in which an access port is implanted. In place of metallic materials some access ports have been fabricated at least in part from biocompatible plastics.

[0015] A further problem relating to the materials for and manufacture of access ports is the deleterious impact of some manufacturing procedures on the fluids which flow through the fluid cavities and related structures located between the fluid cavities and the catheter. During the manufacture of an access port, whether the port is comprised of metallic or plastic materials, it becomes necessary to form the fluid cavities and exit passageways through which the fluid will be directed into the attached catheter.

[0016] This manufacturing process often leaves sharp edges and corners in the areas where the fluid cavity is to direct the flow of the fluid through an exit passageway. As blood or other fluids are injected through the septum into the fluid cavity, pressure developed within the fluid cavity tends to cause fluid to flow through the exit passageway. As the fluid in the fluid cavity flows past the sharp edges and corners produced in a manufacture of the access port, turbulence arises, taking the form of a vortex, adjacent to the sharp edges and corners. Some fluids, such as blood, are sensitive to this turbulence, as lysing of the red blood cell component of the injected blood can occur in these turbulent areas.

[0017] In addition, the machining of the circular fluid cavities often results in the creation of areas within the housing in which fluid flow is retarded. These areas are referred to as dead spaces and usually occur in areas of transition, such as where the bottom of the septum interfaces with the walls of the fluid cavity and where the floor of the fluid cavity meets the exit passageway through which the fluid must flow. As the flow of fluids through dead spaces is retarded, stagnation occurs, resulting in some fluid being trapped within these dead spaces. If the access port is used to transfuse blood, blood trapped in these dead spaces may form clots and block the flow of fluid through the fluid cavity.

[0018] A further problem encountered in the design and construction of access ports, relates to the positioning of the septums within the housing of the access port. The positioning of the septums within the housing is a compromise between two conflicting objectives. These are the need to separate the septums a distance so that the septums may be easily differentiated for the purpose of injection and inherent restriction on the overall dimensions of the access port, which must be placed within a tissue pocket of fairly small dimensions.

[0019] The distancing of the septums to facilitate their differentiation, however, results in a corresponding distancing of the fluid cavities. This result is at odds with another structural requirement for access ports with plural cavities, namely that the exit passageways from each fluid cavity be closely spaced at the point where the implanted catheter is to be coupled to the access port.

[0020] To guide the flow of a fluid from each of the spatially separated fluid cavities into the side-by-side configuration of fluid outflow necessitated by the dimensions of a plural lumen catheter, intermediate structural members have been required. Naturally, this complicates the process of manufacture and increases its cost, as well as the chances of structural failure.

[0021] There are several examples of such intermediate members used to resolve the manufacturing constraints imposed upon the construction of a passageway flowing from spatially separate fluid cavities into a side-by-side configuration acceptable by a catheter.

[0022] One is to produce passageways in the form of bent metal tubes which are then insert molded or welded into the larger body of the access port. The use of such a metal component will interfere with the production of an access port which is free of limits as to the diagnostic imaging techniques that may be used relative to those areas of the body in which an access port is implanted.

[0023] In addition, the non-integral nature of such metal outlet passageways raises the possibility of leakage of medication through the interstices between the metal tubes and the body of the access port.

[0024] Alternatively, to produce fluid flow from spatially separated fluid cavities into the closely spaced lumens of a catheter, each fluid cavity has been designed with its own spatially separated outlet stem. These outlet stems are then coupled by a hub structure for permanent attachment to the closely spaced lumens of a catheter. This type of arrangement increases the size of the overall access port and its cost of manufacture by adding thereto the necessity of fabricating and assembling the hub element.

[0025] Port connections to catheters in this manner are permanent. Accordingly, if the catheter is to be shortened by trimming that trimming must occur at the distal end of the catheter, and this precludes the use thereat of any type of specially designed tip or valve.

[0026] One additional set of problems encountered in the use of access ports relates to the actual connection of the catheter to the access port. This is most commonly effected by securing the catheter to an outlet stem protruding from the housing of the access port. In an attempt to lock the catheter to the outlet stem of the access port, thread-type systems have been developed

wherein the catheter is attached to an outlet stem, and the outlet stem is then threaded into the access port. When utilizing this system, however, it is difficult to determine the amount of engagement of the catheter onto the outlet stem. Some catheter connection systems do not allow visual verification of attachment. As a result, leakage and failure can occur.

[0027] To overcome this problem, access ports are produced in which the catheter is pre-attached at the factory. While this practice alleviates many of the problems with leakage and failure due to catheter slippage, this system severely limits the type of the catheter usable with the access port. As mentioned above, this precludes the use of catheters having specialized distal tips, as the distal end of the catheter is the only end that can then be trimmed to effect its ultimate sizing. For example, catheters utilizing a Groshong (Trade Mark) slit valve at their distal and may not have any of the distal tip of the catheter removed without compromising the catheter.

BRIEF SUMMARY OF THE INVENTION

[0028] In accordance with the invention as embodied and broadly described herein, an implantable dual access port is provided having a housing containing a plurality of open cavities capable of retaining medicinal or other fluids such as blood.

[0029] The housing comprises a base, a septum support, and a cap configured so as to be capable of being fixedly engaged with each other.

[0030] The base has a flat floor and walls normal and upstanding therefrom. The walls define a first fluid cavity and a second fluid cavity. The first fluid cavity at least has a cross-section that is non-circular when taken in a plane parallel to the floor of the base. The septum support is planar and configured to mate with the ends of the walls of the base opposite from the floor of the base. The septum support has formed therethrough a first septum receiving aperture positioned above the first fluid cavity and a second septum receiving aperture positioned above the second fluid cavity. Should it be necessary to utilize an access port configured to have more than two fluid cavities, the planar septum support would, of course, be configured to have formed therethrough a corresponding number of septum receiving apertures.

[0031] The cap is configured to receive the septum support and the base, forming the exterior upper housing. The cap comprises a top wall having formed therein a first septum access aperture at a position opposite the first septum receiving aperture when the septum support and the base are received in the cap.

[0032] A second septum access aperture overlies the second septum receiving aperture when the septum support and the base are received in the cap. A skirt depends from the periphery of the top wall. The skirt encloses the septum support and the walls of the base when the septum support and the base are received in the cap.

[0033] Connected to the access port is an outlet stem in which is formed two internal stem channels. These stem channels communicate respectively through individual exit passageways with the fluid cavities. Each stem channel is longitudinally formed through a separately configured prong. The prongs are separated from each other by an elongated slot that extends from the distal tip of the prongs to a point intermediate the length of the stem.

[0034] Each prong is configured on the exterior thereof with a catheter connection means. By way of example, the catheter connection means in one embodiment is a barb located on each prong, having an approximately semicircular raised surface positioned on the outside wall of the prong near the distal end thereof. The distal face of the raised surface tapers outwardly from the wall of the prong from the distal end toward the proximal end thereof.

[0035] Both prongs are configured so as to be equal to or slightly larger than the inside diameter of the catheter to be connected thereto. When the catheter is slid over the stem, the catheter expands somewhat to snugly engage the stem. A web between the lumens of the catheter enters and engages the sides of the elongated slot between the prongs. The shape of the raised surfaces of the prongs serve to prevent the catheter from slipping off of the stem.

[0036] As a further securement means, a locking sleeve is slid over the engaged catheter and stem. The locking sleeve is sized so as to snugly grip the catheter wall and urge it against the barbs on the outside surface of the stem. This action further tends to push the prongs together thus gripping the web of the catheter in the elongated slot therebetween.

[0037] According to one aspect of the present invention, an access port of the type described is provided with a first interface means for placing the first fluid cavity in fluid flow communication with the corresponding first exit passageway and for directing from the first fluid cavity into the first exit passageway a flow of fluid having a cross-section smoothly reduced in area from the first fluid cavity to the first exit passageway. The first interface means takes the form of a transition region formed between the first fluid cavity and the first exit passageway with walls free of sharp turns or sharp edges. The transition region thus takes on a funnel-shaped configuration in a plane taken parallel to the floor of the base of the access port. When used in combination with a fluid cavity having an otherwise circular cross section in a plane parallel to the floor of the base of the access port, such a transition region results in a fluid cavity having a droplet-shaped cross section.

[0038] The present invention also provides an implantable device having a single tactile means for determining the relative locations of each of two or more septums through the skin of the patient without simulta-

neously blocking access to either of the septums. Any obstruction of access to the septums currently caused by the fingers of medical personnel in the very process of palpating the skin of a patient is eliminated. This is accomplished without resorting to any structure that encircles an area of tissue and would therefore make the tissue encircled thereby susceptible to necrosis.

[0039] By way of example, the surface of the housing of the interface access port is provided with a raised locating ridge positioned so as to be adjacent to and between the two access apertures in which are captured the septums that afford access to the fluid reservoirs associated with each. The locating ridge is preferably configured in a linear manner and oriented so as to be orthogonal to a line joining the centers of the septums. Alternatively, the locating ridge may be configured so as to be parallel to the line joining the centers of the septums.

[0040] Other configurations of the locating ridge are also possible. one such embodiment of the locating ridge comprises a configuration wherein the ends of the linear ridge are enlarged. This serves to facilitate locating the ridge. Alternatively, the ridge may be curved rather than straight, so as to assume an S-shape, or configured in an X-shape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings.

[0042] Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is a perspective view of an implantable access port incorporating teachings of the present invention, including a linear locating ridge on the exterior thereof;

Figure 2 is an exploded perspective view of the elements access port illustrated in Figure 1;

Figure 3 is a plan view ot the base of the access port illustrated in Figure 2;

Figure 4 is a partial breakaway plan view of the stem portion ot the base illustrated in Figure 3;

Figure 5 is a view of the bottom surface of the septum support illustrated in Figure 2;

Figure 6 is a partially broken away, cross-sectional view taken along section line 6-6 in Figure 5;

Figure 7 is an enlarged cross-sectional elevational view of the assembled access port illustrated in Figure 1 taken along section line 7-7 shown therein;

Figure 8 is a cross-sectional, elevational view taken along section line 8-8 in Figure 7 further illustrating the location of the septums and the geometry of the fluid cavities formed within the housing;

Figure 9 is an elevational view of the outlet stem and the exit passageways formed therein when viewed along section line 9-9 in Figure 3;

Figure 10 illustrates the disassembled components of a system for coupling a catheter to the access port of Figure 1;

Figure 11 is a cross-sectional view of the locking sleeve of Figure 10 taken along section line 11-11 shown therein;

Figure 12 is a cross-section of an assembled outlet stem, catheter, and locking sleeve like those illustrated in Figure 10;

Figure 13 illustrates a second embodiment of an implantable access port capable of utilizing a triple lumen catheter;

Figure 14 is a plan view of a third embodiment of the device of Figure 1 with a locating ridge that is S-shaped;

Figure 15 is a plan view of a fourth embodiment of the device of Figure 1 with a locating ridge that is X-shaped;

Figure 16 is a plan view of a fifth embodiment of the device of Figure 1 with a locating ridge that is enlarged at both ends;

Figure 17 is a plan view of a sixth embodiment of the device of Figure 1 with a locating ridge that is laterally positioned between the septums;

Figure 18 is a plan view of a seventh embodiment of the device ot Figure 1 with a locating ridge that is curved and has an appendage pointing towards one of the septums of the device; and

Figure 19 is a plan view ot an eighth embodiment of the device of Figure 1 with a locating ridge that is arrow-shaped at the end thereof adjacent the stem of the device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0043] A perspective view of one embodiment of an implantable access port 10 incorporating teachings of the present invention is shown in Figure 1. Access port 10 generally comprises a housing 11 which is itself comprised of three plastic components that are bonded to each other. Only two of these components, a base 12 and a cap 14, appear in Figure 1.

[0044] During assembly, a septum support is bonded to the base after which the septums are inserted into the septum support and the cap is placed over the septum support and the walls upstanding from the base. After assembly, the bottom of the cap and the base may be bonded to form a fluid-tight joint.

[0045] In an alternate method of bonding the components of the access port involves bonding at the area surrounding the septums. After the cap has been placed over the septums, the areas near the top of the cap may be bonded to the septum support which has previously been bonded to the base.

[0046] Access port 10 also comprises a plurality of self-sealing septums, such as self-sealing septums 17 and 18, and an outlet stem not shown in Figure 1 by which a catheter 70 is coupled to access port 10 and placed in fluid communication with fluid cavities interior thereto.

[0047] Catheter 70 is a dual lumen catheter with the lumens 72 and 74 thereof, separated by a web 76.

[0048] A locking sleeve 80 enhances the lock of a catheter 70 over an outlet stem (not pictured).

[0049] In use, the distal end of catheter 70 is entered into a major vessel of the cardiovascular system of a patient and advanced therefrom, for example, into a position at the superior vena cava. After catheter 70 is thusly positioned, sufficient slack to allow for normal body movement without straining catheter 70 is left in the point of entry of catheter 70 into the vascular system. The free end of catheter 70 is then tunneled from its point of entry into the vascular system to a pocket in the tissue of a patient. The catheter is then attached to the access port, and the access port is secured into the pocket using sutures installed through suture holes 13 formed in a flange 19 about base 12. Generally, access port 10 is placed in the chest wall (infraclavicular) on either the right or the left side supported by the underlying ribs. A pocket incision is made about the length and diameter of base 12. Preferably, access port 10 is buried only about 0.50 inches (1.25 cm) below the skin, which is generally sufficient to prevent access port 10 from eroding through the skin. The pocket is then closed.

[0050] Septums 17 and 18 are configured such that they may be punctured by a non-coring needle, and resealed after the needle has been removed. Septums 17 and 18 are therefore constructed from a self-sealing polymer such as silicone rubber or latex.

[0051] According to one aspect of the present invention, the housing 11 of an access port, such as access port 10, is provided with tactile means for determining the relative locations of septums 17 and 18 through the skin of a patient without simultaneously blocking access to either of septums 17 or 18. By way of example and not limitation as shown in Figures 1 and 2, a raised locating ridge 24 protrudes upwardly from cap 14. Locating ridge 24 is positioned between and closely adjacent to septums 17 and 18. In the embodiment shown in Figure 1, raised ridge 24 is substantially linear and is oriented so as to be orthogonal to a line joining the centers of septums 17 and 18. Such a configuration is, however, only exemplary, as various other configurations of a locating ridge are considered to fall within the scope of the present invention. Several will be disclosed subsequently relative to Figures 14-19.

[0052] One important aspect of locating ridge 24 is that locating ridge 24 does not encircle any enclosed area of tissue. This eliminates the possibility of blood restriction and the necrosis of tissue.

[0053] Once a physician has located raised ridge 24, the physician immediately knows the location of both septums 17 and 18 on either side of locating ridge 24. It is not necessary for the physician to locate one septum, and then to have to search further for the additional of the septums. Using locating ridge 24 the septums can be located by tactile sensation without at the same time impeding access to the septums for the purpose of effecting an injection therethrough.

[0054] Access port 10 is constructed of a plastic material which does not interfere with MRI or CAT scan diagnostic imaging. Cap 14 is comprised of a top wall 16 having formed therein a first septum access aperture 51 at a position opposite a first fluid cavity (not shown) in base 12 when base 12 is received in cap 14. A second septum access aperture 51a is also formed in top wall 16, but at a position opposite a second fluid cavity (not shown) in base 12 when base 12 is received in cap 14. A skirt 15 depends from top wall 16 of cap 14 to enclose base 12 when base 12 is received in cap 14.

[0055] Septums 17 and 18 are captured in access apertures 51, 51a sealing but affording access to the fluid cavities located thereunder. Septums 17 and 18 are needle-penetrable, while the remaining portions of access port 10 are needle-impenetrable. Cap 14 is ultrasonically welded after assembly to base 12 either at top wall 16 about septums 17 and 18 or at the bottom of skirt 15.

[0056] A more complete depiction of the components of access port 10 is found in the exploded view thereof depicted in Figure 2. There, access port 10 is shown to include not only base 12 and cap 14, but a septum support 26 which is disposed therebetween. Also in Figure 2, catheter 70 is shown disconnected from an outlet stem 20 by which access port 10 and catheter 70 are connected when implanted. The interaction of locking sleeve 80, catheter 70, and outlet stem 20 will be dis-

cussed in more detail later in the description, in connection with Figures 9-12.

[0057] Base 12 has a flat floor 39 and generally curved walls 41 normal to and upstanding therefrom. Walls 41 define a first fluid cavity 40 and a second fluid cavity 42 having non-circular cross sections when taken at a plane parallel to floor 39. This is illustrated to better advantage and discussed at length subsequently relative to Figures 3 and 4.

[0058] A septum support shelf 43 serves as a stop for septum support 26 when septum support 26 is assembled on base 12. A dividing wall 44 separates fluid cavity 40 from fluid cavity 42. Dividing wall 44 shares the same longitudinal axis as slot 28 between prongs 54, 56 of outlet stem 20. Dividing wall 44 in combination with upstanding walls 41, forms a non-circular perimeter for cavities 40 and 42 in base 12 of housing 12.

[0059] Recessed walls 45 extend upward beyond septum support shelf 43 to receive the outer surface of septum support wall 46 on the side of septum support 26 that nests against base 12. Upon engagement of septum support 26 with septum support shelf 43 and recessed walls 45, the lower inner side 47 of wall 41 meets flush with the lower inner side of septum support wall 46. Thereafter, septum support 26 is bonded to base 12 preferably by ultrasonic welding. Nevertheless, in lieu thereof alternate forms of bonding, such as adhesive bonding, may be utilized.

[0060] Septums 17 and 18 are then inserted into septum receiving apertures 49. In so doing, fluid cavities 40 and 42 become sealed. Fluid cavities 40 and 42 are then bounded by floor 39, lower inner side-wall 47, lower inner side-wall 48, and the bottom surface of septums 17 or 18.

[0061] It should be noted at this point that the cross-sectional shape of fluid cavities 40 and 42 as illustrated in Figure 3, for example, are definitively non-circular. It is one function of septum support 26 to permit the use of circular septums, such as septums 17 and 18, in conjunction with a non-circular fluid cavity, such as fluid cavities 40 and 42. Advantageously, a circular septum such as septums 17 and 18, can be easily subjected to radially uniform support and compression, whereas a non-radially symmetric septum, such as one designed to conform to the cross section of a non-circular fluid cavity, will be difficult to load in a radially uniform manner.

[0062] The radially uniform support and compression of a septum contributes to the equal distribution of stresses therein and to long-term, non-destructive penetration by non-coring needles.

[0063] Although much of the following discussion, for simplicity, centers around one or the other of fluid cavities 40 and 42, both cavities share the same construction. A structure in one fluid cavity is mirrored by a similar structure in the adjacent fluid cavity, as base 12 is symmetrical when viewed along a line drawn through the common longitudinal axis of dividing wall 44 and slot 28.

[0064] After septums 17 and 18 are inserted into septum receiving apertures 49, cap 14 is placed over septum support 26 and walls 41 of base 12 to enclose those structures. The bottom surface of skirt 15 of cap 14 abuts flange 19 on the exterior of walls 41. When cap 14 is bonded to base 12, the upper surfaces 64 of septums 17 and 18 protrude through access apertures 51 and 51a in top wall 16. Outlet stem 20 protrudes from a shoulder 78 on base 12 which is received in a stem arch 53 formed in skirt 15. Septums 17 and 18 are received in septum receiving apertures 49 through the engagement of the bottom surface and sides of a septum perimeter ring 55 with the walls and top surface of a perimeter ring shelf 61 on septum support 26.

[0065] Likewise, septums 17 and 18 are retained in septum support 26 by downward pressure exerted from the engagement of the top of perimeter ring 55 by an outer perimeter 63 of access aperture 51. This allows upper surfaces 64 of septums 17 and 18 to extend beyond the top wall 16 of cap 14 and, thereby, remain accessible to a physician.

[0066] Figure 3 is a plan view of base 12 illustrating in further detail the configuration of fluid cavities 40 and 42. Lower inner side-wall 47 comprising a circular arc ACB combines tangentially with both straight normal wall portion 68a and S-shaped convex curved wall portion 69a to form a non-circular perimeter to fluid cavity 42. Fluids injected through one of septum 18 enter fluid cavity 42 and travel through a transition region 65a which bounded by minor arc AB shown in dashed lines, straight normal wall portion 68a, and S-shaped convex curved wall portion 69a.

[0067] As illustrated by the arrows F in Figure 4, the flow of the fluid out of fluid cavity 40 is directed to an exit passageway 50 located in the narrowest portion of transition region 65 and from there through the exit passageway 67 to egress point 66 at the distal tip 57 of prong 56 of outlet stem 20.

[0068] Figure 4 illustrates a broken-away portion of outlet stem 20 showing the internal structures thereof, such as exit passageways 50 and 52, stem exit passageway 67 and 67a, and egress points 66 and 66b at distal tips 57 of each, of prongs 54 and 56. Exit passageways 50 and 52 communicate respectively through stem exit passageways 67a and 67 in stem 20 with fluid cavities 40 and 42, respectively. Each stem exit passageway 67, 67a is longitudinally formed through a separately configured prong 54, 56, respectively.

[0069] Taken together, transition region 65 and 65a function as outlet means for placing fluid cavity 40 and fluid cavity 42 in fluid flow communication, respectively, with exit passageway 50 and 52 and for directing from fluid cavity 40 and fluid cavity 42, respectively, into each respective exit passageway a fluid flow having a cross section smoothly reduced in area from each fluid cavity to the exit passageway corresponding thereto.

[0070] When a needle is inserted through either sep-

tum 17 or 18 into respective fluid cavity 40 or 42, and fluid is injected there into, fluid flows out of fluid cavity 40 or 42 through transition region 65 or 65a and into stem channel 67 or 67a. The velocity of flow increases in transition regions 65, 65a and is maximized at exit passageways 50 or 52. The velocity or flow rate remains constant through stem exit passageways 67 or 67a to egress points 66 or 66a at distal tips 57 of prongs 54, 56.

[0071] Transition region 65 shares floor 39 of base 12 with the fluid cavity 42. The sides of transition region 65, however, do not share the generally circular configuration of lower inner side wall 47 encircling fluid cavity 42.

[0072] Instead, transition region 65 is bounded by a normal wall portion 68 disposed normal to exit passageway 50 and a convex curved wall 69 which directs the flow through fluid cavity 42 in a direction toward exit passageway 52.

[0073] Normal wall portion 68 and convex curved wall portion 69 together therefore define a transition region 65 having a cross-section that gradually reduces in area from fluid cavity 40 to exit passageway 50. It is an important aspect of the present invention that the combination of gently curved or straight walls at transition regions 65 or 65a minimizes sharp turns or edges, as well as dead spaces, in the flow of fluid out of access port 10. Once fluid has entered stem exit passageways 67 or 67a, the parallel, straight sides thereof provide a smooth passageway in which the fluid may flow.

[0074] Outlet stem 20 is formed integrally with base 12, thereby obviating any chances of leakage occurring between outlet stem 20 and base 12. No intermediate structures are required to be placed between exit passageways 50 or 52 and egress points 66 or 66a to redirect the flow of fluid from spatially separated fluid cavities 40 and 42 into the lumens of an attachable catheter. The absence of such an additional member is achieved by configuring fluid chamber 42 so that exit passageway 52 is positioned at a distance from the axis of slot 28 equal only to one-half of the thickness of web 76 of catheter 70. Correspondingly, fluid chamber 40 is configured so that exit passageway 50 is positioned at a distance from the axis of slot 28 equal only to one-half of the thickness of web 76 of catheter 70.

[0075] According to one aspect of the present invention, transition regions 65 and 65a comprise respectively first and second interface means for placing fluid cavities 40 and 42 and fluid flow communication with exit passageways 50 and 52, respectively and for directing from each respective fluid flow cavity into the exit passageway communicating therewith a flow of fluid having a cross-section that is smoothly reduced in area from the fluid cavity to the exit passageway. Transition region 65 and 65a thus take the form generally of a funnel having a large end thereof adjacent to and communicating with fluid cavity 40 or 42 and having the small end thereof adjacent to and communicating with exit passageway 50 or 52, respectively.

[0076] As seen in overall perspective in the plan view of Figure 3, each of fluid cavities 40 and 42 have a cross-section in a plane parallel to floor 39 of base 12 which comprises, in combination, a circle and a wedge-shaped appendage in the form of transition region 65 or 65a, having a vertex and first and second sides adjacent thereof.

[0077] In each instance, the vertex of the wedge-shaped appendage is located at exit passageway 50 or 52, respectively, away from the circular portion of the cross-section of each respective fluid cavity.

[0078] The first and second sides adjacent to the vertex join the circular portion of the cross-section at the circumference thereof. The first side of the appendage is linear, comprising normal wall portion 68, while the second side of the appendage is S-shaped, comprising convex curved wall portion 69.

[0079] Taken in another perspective, the cross-section of fluid cavity 40, 42 taken in a plane parallel to floor 39 of base 12 comprises a generally round portion substantially circled by lower inner side 47 of walls 41, a generally pointed portion remote from the round portion, and a transition region smoothly connecting the round portion to the pointed portion. In the embodiment illustrated in Figure 3, fluid cavities 40, 42 assume a droplet-shaped cross-section. The pointed portion of the cross-section of fluid cavities 40, 42 comprises the narrow terminus of transition regions 65, 65a at the outlet passageways. These pointed portions are disposed on the sides of fluid cavities 40 and 42 adjacent to each other, so as to terminate at a distance from each other substantially equal to the lateral separation of lumens 72, 74 of catheter 70 or egress points 66, 66a of outlet stem 20.

[0080] In other words, exit passageways 50 and 52 in the present invention are spaced apart a distance equal approximately to the width of slot 28 or web 76 between lumens 72 and 74 of catheter 70. Having exit passageways 50 and 52 so closely positioned eliminates the need for any prior art intermediary member to transition the passageways from spatially separated fluid cavities to a proximity at which a catheter may be attached directly thereto. In addition, the flow of fluid achieved out of access port 10 is free from the circuitous paths, sharp edges, or dead spaces produced by the use of such intermediary members.

[0081] Figure 5 is a view of the bottom surface of septum support 26. It is the bottom surface of septum support 26 which nests with the tops of walls 21 of base 12 to form the fluid cavities 40 and 42. Lower inner sidewall 48 of septum receiving aperture 49 forms the upper side-wall surface of fluid cavity 42. When viewed from the bottom surface as in Figure 5, the structures forming the top of transition regions 65 and 65a may be clearly seen. Similar to the corresponding walls 41 of base 12, the normal wall portions 68 and convex curved wall portion 69 guide fluid flowing from fluid cavity 42 into exit passageway 52.

[0082] As can be seen in Figure 5, transition provides a funnel-shaped approach to exit passageway 50 which is free from sharp turns and edges. The rate of flow through transition region 65 increases as the cross-sectional area of transition region 65 is reduced. Transition region 65 is free of sharp edges and turns, which can cause turbulence and dead spaces, which can trap stagnant fluid within the fluid cavity.

[0083] Figure 6 is partially broken away enlarged view of the bottom surface of septum support 26 illustrating a receiving groove 73 so shaped and sized so as to be capable of receiving dividing wall 44 of base 12. It is important to note that receiving groove 73 is very narrow, thus affording the minimum separation possible between fluid cavities 40 and 42 at the point at which transition regions 65 and 65a taper to the smallest cross-sectional area thereof at exit passageways 50 and 52, respectively. This minimal separation allows the exit passageways formed in the sides of the fluid cavities to be positioned in side-by-side configuration without the need for an intermediate structure to direct a pair of more distantly positioned exit passageways into a similar side-by-side configuration.

[0084] When assembled, receiving groove 73 on septum support 26 is filled by dividing wall 44 on base 12 and ultrasonically bonded therein.

[0085] The use of ultrasonic bonding processes to secure base 12, cap 14 and septum support 26 imposes certain structural constraints upon these components of housing 11. In a general sense, the walls of each of these three components of housing 11 must be of substantially similar thickness. In this manner, during ultrasonic bonding, all regions of the three components of housing 11 will absorb a relatively similar quantity of ultrasonic energy per volume , thereby reaching similar temperatures simultaneously.

[0086] For this reason, none of base 12, cap 14, or septum support 26 include any substantially bulky regions, and it is toward this end, for example, that base 12 is provided with a void 22 and septum support 26 is provided with a void 23 in the regions thereof intermediate fluid cavities 40 and 42 as shown in Figures 2 and 3.

[0087] Additionally, because ultrasonic bonding results in the generation on an almost immediate basis of molten portions of the components to be bonded, and inasmuch as those molten portions thereof tend to expand, the mating faces of base 12, cap 14 and septums 17 and 18 are provided with various voids into which such moltenized plastic can expand.

[0088] Thus, for example, as seen to best advantage in Figure 5 and thereafter in Figures 6-8, septum support wall 37 on the lower surface of septum support 26 is encircled by a recessed flash channel 79 into which such molten plastic can expand. In this manner, molten plastic does not force apart the components being bonded together and such molten plastic flows into spaces such as flash channel 79, in preference to critical areas, such as fluid cavities 40 and 42.

[0089] Recesses 75 form the roofs of transition regions 65 and 65a when septum support 26 is affixed to base 12. Convex curved wall portion 69 has an upper portion 77 which is shaped identically to convex curved wall 69 of base 12. By joining these two walls upon assembly, transition regions 65 and 65a remain free of sharp ends and edges and directs the flow of fluid smoothly into the exit passageways.

[0090] Figure 7 is a cross-sectional view of an assembled access port 10, such as that illustrated in Figure 1. There, fluid cavity 42 is shown to be enclosed by floor 39 and lower inner side wall 47 of base 12, as well as lower side wall 48 of septum support 26 and a bottom surface 71 of septum 18. Transition region 65 shown in Figure 7 to the right of the circular portion of fluid cavity 42 is shown presenting convex curved wall portion 69 to direct the flow of fluid smoothly to the right as shown in Figure 7 into the region of reduced cross-sectional area of transition region 65 at exit passageway 52 (not shown).

[0091] Also depicted in Figure 7 is the interaction of cap 14, septum support 26, and base 12 to form the housing 11 surrounding fluid chamber 40. When engaged, septum support 26 is in contact with septum support shelf 43. Septum 17 is supported on perimeter ring shelf 61 of septum support 26 and is permanently held down on perimeter ring shelf 61 by outer perimeter 63 of access aperture 51 in cap 14. Septum 17 is preferably held in place by the bonding of cap 14 to the top of septum support 26 or by the body of the bottom surface of skirt 15 to flange 19 of base 12.

[0092] Figure 8 is a cross-sectional view taken along section line 8-8 in Figure 7 to further illustrate transitional areas 65 and 65a. Septum 17 and 18 are retained between perimeter ring shelf 61 of septum support 26 and outer perimeter 63 of access aperture 51 located in cap 14. Fluid cavity 42 is shown formed between bottom surface 71 of septum 18, lower inner side wall 47 of wall 41, lower inner side wall 48 of septum support 26, and floor 39 of base 12. Normal wall portions 68 are shown adjacent each of exit passageways 50 and 52 in the transition regions 65 and 65a approaching those exit passageways. As can be seen in Figure 8, sharp turns or edges are minimized to fluid flowing from fluid cavity 42 into exit passageway 52.

[0093] In use, a needle pierces septum 18 and fluid may then be injected into fluid cavity 42 for advancement through transition region 65a to exit passageway 52. In transition region 65, however, turbulence and vortex action is kept to a minimum and stagnation areas are avoided.

[0094] Figure 9 illustrates an end view of outlet stem 20 having formed in each of prongs 54 and 56 thereof stem channels 67 and 67a. Slot 28 defined between prongs 54 and 56 is capable of receiving web 76 of multi-lumen catheter 70. Although the outlet stem illustrated in Figure 9 is configured for use in a dual-lumen catheter having lumens which are generally D-shaped,

catheters having a plurality of lumens having other configurations and correspondingly shaped prongs on an outlet stem also fall within the scope of the present invention. In each instance, the number and shape of stem channels 67 and the outer surfaces forming the prongs thereabout are configured so as to correspond with the number and shape of the lumens of the catheter to be slid over the prongs.

[0095] Figure 10 is a plan view of outlet stem 20 of Figure 9 showing in disassembled state therewith catheter 70 and locking sleeve 80. These are also illustrated in Figure 2. To assemble these elements, the proximal end 88 of catheter 70 is slid over the distal tip 57 of prongs 54 and 56. As the outer diameter of prongs 54 and 56 at distal tip 57 is smaller than the internal diameter of catheter 70 at this point, a small amount of pressure is needed to engage catheter 70 over distal tip 57.

[0096] Continued pressure in the direction toward housing 11, will, however, force catheter 70 onto barb ramps 31 and 31a on barbs 60 and 62, respectively. The tip 90 of barbs 60 and 62 represents the region wherein barbs 60 and 62 have the greatest circumference. The circumference of barbs 60 and 62 at tip 90 is greater than the inside diameter of catheter 70. As a result, a great degree of resistance to the advancement of catheter 70 arises at tips 90.

[0097] Further pressure on catheter 70 in the direction of housing 11 causes proximal end 89 of catheter 70 to pass over tips 90 and onto a reduced region 32 having an outer circumference that is less than the inner-circumference of catheter 70. Little resistance to the advancement of catheter 70 is encountered in this area.

[0098] As catheter 70 is advanced farther onto outlet stem 20, proximal end 88 of catheter 70 encounters a ramped surface 33, having a ramp of gradually increasing circumference terminating in a renitent surface 34. Renitent surface 34 has a circumference greater than the internal circumference of catheter 70.

[0099] Catheter 70 is inserted over outlet stem 20 to a point where the inner web 76 of the dual lumen catheter encounters the end of slot 28. Locking sleeve 80 is then slid along catheter 70 and pressed onto outlet stem 20.

[0100] Figure 11 is a cross-sectional view taken along section line 11-11 in Figure 10 further depicting the inner structure of the locking sleeve 80. Although many configurations of locking sleeves fall within the scope of the present invention, a locking sleeve 80 is utilized in a presently preferred embodiment of the instant invention having on the exterior thereof a pressure application ridge 102 which provides a ridge upon which a physician may press when forcing locking sleeve 80 over catheter 70 and outlet stem 20.

[0101] To install locking sleeve 80 over catheter 70, a proximal end 104 thereof is slid over the portions of catheter 70 covering barbs 60 and 62 until proximal end 104 encounters the portion of the catheter covering ramped surface 33. As the diameter of the opening of locking sleeve 80 at proximal end 104 is greater than the diameter of tip 90 and reduced area 32, no pressure is exerted by proximal end 104 until proximal end 104 encounters the portion of the catheter covering the ramped surface 33.

[0102] Before proximal end 104 reaches ramped surface 33 and renitent surface 34, however, an internal ramp 106 of locking sleeve 80 begins to encounter other structures of outlet stem 20 covered by catheter 70. The diameter A of the inside of locking sleeve 80 at the narrowest point 100 of internal ramp 106 is slightly less than the diameter of tip 90 of barbs 60 and 62 when catheter 70 is slid thereover. As a result, as internal ramp 106 encounters the catheter covering tip 90 of barbs 60 and 62, increased resistance is encountered to the advancement of locking sleeve 80.

[0103] As internal ramp 106 is pressed over tips 90 of barbs 60 and 62, however, the narrowest point 108 of internal ramp 106 passes to the side of tips 90 adjacent to housing 11. From narrowest point 108 of internal ramp 106 to distal end 110 of locking sleeve 80, the internal diameter B thereof becomes progressively larger than diameter A. This difference between diameters A and B thus concentrates the compression of the catheter at or proximal of the barbs. As a result, energy must be introduced to remove the locking sleeve from the portion of the catheter located above the barbs. Thus, once narrowest point 108 has passed over tips 90 of barbs 60 and 62, the internal configuration of locking sleeve 80 tends to bias locking sleeve 80 to remain in position on stem 20.

[0104] The radial pressure exerted inwardly by the locking sleeve compresses barbs 54 and 56 into slot 28. This then compresses web 76 of catheter 70. The region above the barbs produces the most renitent force. This area of greatest compression also sealingly compresses the barbs against the web of the catheter.

[0105] The access port is provided with means for biasing the locking sleeve into a locking position on the outside of the catheter when the proximal end of the catheter is received on the outlet stem. By way of example and not limitation, the means for biasing provided in the embodiment illustrated in Figure 11 comprises locking sleeve 80, internal ramp 106, and a gradually tapering surface, delineated by the surface between diameter arrow A and diameter arrow B in Figure 11. The gradually tapering surface requires the input of energy to remove the locking sleeve from the catheter.

[0106] Figure 12 illustrates locking sleeve 80 in its assembled position over catheter 70 on outlet stem 20. Proximal end 104 of locking sleeve 80 is shown abutted against a face 38 of shoulder 78. As the proximal end 88 of catheter 70 does not extend to this point, no pressure is exerted on outlet stem 20 there.

[0107] An area of substantially uniform pressure exists in the region where catheter 70 is in contact with renitent surface 34. Pressure exerted on prongs 54 and 56 increases in the region where internal ramp 106 is positioned in contact with ramped surface 33. As this

radial pressure from the outer walls of catheter 70 forces prongs 54 and 56 together, pressure is exerted therebetween on web 76 located in slot 28 thereby sealing the interface therebetween.

[0108] The area of greatest pressure occurs in the region surrounding tip 90 of barb 60 and 62. Although the internal diameter of the locking sleeve is increasing at this point, the presence of barbs 60 and 62 greatly reduces the distance between the outer surface of prongs 54 and 56 and the inner surface of locking sleeve 80. This insures that catheter 70 and locking sleeve 80 will be retained on outlet stem 20.

[0109] By way of example and not limitation, a triple-cavity access port 85 capable of being utilized with a triple lumen catheter is illustrated in Figure 13. Septums 81 are shown captured within the housing 82 thereof enclosing three fluid cavities (not pictured). An outlet stem 87 comprised of three prongs 83 provides support for a triple lumen catheter (not shown) having generally wedge or triangular shaped lumens. These communicate through egress points 84 of an exit passageway in each of outlet stems 83. Pressure exerted by the exterior wall of the catheter against the sides of prongs 83 urges these into a Y-shaped slot 86 which is filled with a Y-shaped web when a catheter is slid over this outlet stem.

[0110] Figures 14-19 illustrate various embodiments of locating ridges contrasted with the locating ridge 24 illustrated in Figures 1 and 2. Each locating ridge outlines to some degree the configuration of one or both of septums 17 and 18 positioned adjacent thereto.

[0111] As an example, Figure 14 depicts a third embodiment of an access port provided with a locating ridge 24a having an S-shape. Figures 15 and 16 depict locating ridges 24b and 24c, respectively, having enlarged ends. Figure 17 depicts a linear locating ridge 24d disposed parallel to and in line with a line joining the centers of septums 17 and 18. It is important to note, however, that septums 17 and 18 are not completely enclosed by locating ridge 24, since this could result in necrosis of the tissues thusly encircled.

[0112] In Figure 18, locating ridge 24e further comprises a first indicator means for identifying the relative direction from locating ridge 24e of one of septums 17 or 18. As shown by way of example in Figure 18, appendage 25 extends from the outer curve of locating ridge 24e toward septum 18.

[0113] As shown in Figure 19, a second indicator means is provided for identifying the location of stem 20 relative to septums 17 and 18. There otherwise linear locating ridge 24f is provided at the end thereof adjacent to stem 20 with an enlarged head 25a taking the form of an arrow.

[0114] Utilizing appendage 25 or appendage 25a, a physician palpating the location of the access port through the skin of a patient can be provided with information about the relative location of various structure elements of the access port.

Claims

1. An implantable access port capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a dual lumen catheter, said access port comprising:

    (a) a needle-impenetrable base having a flat floor and walls normal to and upstanding therefrom, said walls defining a first fluid cavity and a second fluid cavity;
    (b) a septum support configured to mate with the free ends of said walls of said base opposite from said floor thereof, said septum support having formed therethrough a first septum receiving aperture positioned opposite said first fluid cavity when said septum support mates with said free ends of said walls of said base an a second septum receiving aperture positioned opposite said second fluid cavity when said septum support mates with said free ends of said walls of said base; and
    (c) a needle-impenetrable cap configures to receive said septum support and said base, said cap comprising a top wall having formed therein:

        (i) a first septum access aperture communicating through said top wall of said cap at a position opposite said first septum receiving aperture when said septum support is received in said cap, said first septum access aperture and said first septum receiving aperture together defining a first access aperture communicating with said first fluid cavity; and
        (ii) a second septum access aperture communicating through said top wall of said cap at a position opposite said second septum receiving aperture when said septum support is received in said cap, said second septum access aperture and said second septum receiving aperture together defining a second access aperture communicating with said second fluid cavity;

    (d) a first needle-penetrable septum captured between said septum support and said cap sealing said first access aperture; and
    (e) a second needle-penetrable septum captured between said septum support and said cap sealing said second access aperture.

2. An access port as recited in claim 1, wherein the

cross-section of said first fluid cavity and the cross-section of said second fluid cavity taken in a plane parallel to said floor of said base differ in shape from the cross-section of said first septum receiving aperture and the cross-section of said second septum receiving aperture, respectively.

3. An access port as recited in claim 2, wherein said cross-section of said first septum receiving aperture and said cross-section of said second septum receiving aperture are circular.

4. An access port as recited in claim 2, wherein said cross-section of said first fluid cavity and said cross-section of said second fluid cavity are non-circular.

5. An access port as recited in any one of the preceding claims, wherein said base, said septum support, and said cap are ultrasonically bonded to form a needle-impenetrable housing.

6. An access port as recited in any one of the preceding claims, wherein said cap further comprises a skirt depending from the periphery of said top wall of said cap, said skirt enclosing said septum support and said walls of said base when said septum support and said base are received in said cap.

7. An access port as recited in claim 6, further comprising an outlet stem connected at a proximal end thereof with said housing and configured at a distal end thereof to receive the proximal end of the catheter.

8. An access port as recited in claim 7, wherein said outlet stem is integrally formed with said base.

9. An access port as recited in claim 7 or 8, wherein said outlet stem projects through said skirt of said cap generally parallel to said floor of said base when said base is received in said cap.

10. An intermediate article of manufacture for assembly with a needle-impenetrable base and a needle-impenetrable cap to form an implantable access port capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of a patient and the proximal end of a selected one of the lumens of a dual lumen catheter, the base having a flat floor and walls normal to and upstanding therefrom, the walls defining a first fluid cavity and a second fluid cavity, the cap having a top wall having formed therethrough a first septum access aperture and a second septum aperture, a first needle-penetrable septum and a second needle-penetrable septum being captured in each of the first septum access aperture and the second septum access aperture, respectively, when the cap and the base are assembled, thereby to seal with the first septum and the second septum access through the cap to the first and second fluid cavities, respectively, said intermediate article of manufacture comprising a septum support configured for assembly intermediate said base and said cap, said septum support together with the cap serving to effect the capture of the first septum and the second septum.

11. An intermediate article of manufacture as recited in claim 10, wherein said septum support comprises a generally planar structure configured to mate with the ends of said walls of said base opposite from said floor thereof.

12. An intermediate article of manufacture as recited in claim 11, wherein said septum support has formed therethrough:

(a) a first septum receiving aperture positioned intermediate said first fluid cavity and said first septum receiving aperture when said base, said septum support, and said cap are assembled; and
(b) a second septum receiving aperture positioned intermediate said second fluid cavity and said second septum receiving aperture when said base, said septum support, and said cap are assembled.

13. An implantable access port capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a dual lumen catheter, said access port comprising:

(a) a needle-impenetrable housing enclosing a first fluid cavity and a second fluid cavity, said housing defining a first access aperture communicating through said housing with said first fluid cavity and a second access aperture communicating through said housing with said second fluid cavity;
(b) a first needle-penetrable septum captured by said housing and sealing said first access aperture;
(c) a second needle-penetrable septum captured by said housing and sealing said second access aperture;
(d) an outlet stem connected at a proximal end thereof with said housing and being configured at a distal end thereof to receive the proximal end of the catheter, said stem enclosing a first

stem channel and a second stem channel, said first and second stem channels extending in side-by-side relationship between said distal and said proximal ends of said stem, the proximal ends of said first and second stem channels being separated laterally a distance substantially equal to the lateral separation of the lumens in the catheter;

(e) a first exit passageway formed in said housing communicating with said proximal end of said first stem channel; and

(f) first interface means for placing said first fluid cavity in fluid flow communication with said first exit passageway and for directing from said first fluid cavity into said first exit passageway a flow of fluid having a cross-section smoothly reduced in area from said first fluid cavity to said first exit passageway.

14. An access port as recited in claim 13, further comprising:

(a) a second exit passageway formed in said housing communicating with said proximal end of said second stem channel; and

(b) second interface means for placing said second fluid cavity in fluid flow communication with said second exit passageway and for directing from said second fluid cavity into said second exit passageway a flow of fluid having a cross-section smoothly reduced in an area from said second fluid cavity to said second exit passageway.

15. An access port as recited in claim 14, wherein said first interface means and said second interface means are located within said housing on adjacent sides of said first fluid cavity and said second fluid cavity, respectively.

16. An access port as recited in claim **14** or **15**, wherein said first interface means comprises a transition region formed between said first fluid cavity and said first exit passageway.

17. An access port as recited in claim 16, wherein said transition region has walls free of sharp turns.

18. An access port as recited in claim 16 or 17, wherein said transition region has walls free of sharp edges.

19. An access port as recited in any one of claims 16, 17 and 18, wherein said transition region takes the form generally of a funnel having the large end thereof adjacent to and communicating with said first fluid cavity and the small end thereof adjacent to and communicating with said first exit passageway.

20. An access port as recited in any one of claims 13 to 19, wherein the longitudinal axis of said outlet stem is disposed in a plane normal to and bisecting of a line connecting the centre of said first fluid cavity with the centre of said second fluid cavity.

21. An access port as recited in any one of claims 13 to 20, wherein said first and said second stem channels are linear and are disposed in parallel relationship to each other.

22. An access port as recited in any one of claims 13 to 21, wherein said first and said second stems channels are elliptical in cross-section.

23. An access port as recited in any one of claims 13 to 22, wherein said housing comprises:

(a) a base having a generally planar flat floor and side walls normal to an upstanding therefrom, said walls defining said first fluid cavity and said second fluid cavity, said first fluid cavity having a cross-section in a plane parallel to said floor of said base that is non-circular;

(b) a planar septum support configured to mate with the ends of said side walls of said base opposite from said floor of said base, said septum support having formed therethrough a first septum receiving aperture positioned above said first fluid cavity and a second septum receiving aperture positioned above said second fluid cavity; and

(c) a cap configured to receive said septum support and said base, said cap comprising:

(i) a top wall disposed opposite said floor and being generally parallel thereto; the top wall having formed therein a first septum access aperture at a position opposite said first septum receiving aperture when said septum support and said base are received in said cap and a second septum access aperture overlying said second septum receiving aperture when said septum support and said base are received in said cap; and

(ii) a skirt depending from the periphery of said top wall, said skirt enclosing said septum support and said walls of said base when said septum support and base are received in said cap.

24. An access port as recited in claim 23, wherein said first access aperture and said second access aperture are formed through said top wall of said housing, and wherein the cross-section of said first and second access apertures is circular.

25. An access port as recited in claim 23 or 24, wherein the cross-section of said first fluid cavity taken in a plane parallel to said floor of said housing is non-circular.

26. An access port as recited in claim 23, 24 or 25, wherein the cross-section of said first fluid cavity in a plane parallel to said floor of said housing comprises in combination:

(a) a circle; and
(b) a wedge-shaped appendage having a vertex and first and second sides adjacent thereto, said vertex of said appendage being directed away from said circle with said first and second sides of said appendage joining said circle at the circumference thereof.

27. An access port as recited in claim 26, where said first side of said appendage is linear.

28. An access port as recited in claim 26 or 27, wherein said second side of said appendage is S-shaped.

29. An access port as recited in any one of claims 23 to 28, wherein said side walls upstanding from said floor of said base further comprise a dividing wall separating said first fluid cavity from said second fluid cavity, said dividing wall having a thickness substantially equal to the lateral separation of the lumens of the catheter.

30. An access port as recited in any one of claims 23 to 29, wherein said first fluid cavity has a droplet-shaped cross-section in a plane parallel to said base of said housing.

31. An access port as recited in any one of claims 23 to 30, wherein said cross-section of said first and second fluid cavities in a plane parallel to said base of said housing comprise:

(a) a generally round portion;
(b) a generally pointed portion remote from said round portion; and
(c) a transition region smoothly connecting said round portion to said pointed portion.

32. An access port as recited in claim 31, wherein said pointed portion of said cross-section of said first and second fluid cavities terminates at a distance from each other substantially equal to the lateral separation of the lumens in the catheter.

33. An implantable access port capable of being implanted beneath the skin of a patient, the access port enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a multi-lumen catheter, said access port comprising:

(a) a needle-impenetrable housing enclosing a plurality of fluid cavities, said housing defining for each of said fluid cavities an individual access apart communicating through said housing with each of said fluid cavities;
(b) a plurality of needle-penetrable septums, each of said septums being captured by said housing and sealing an individual one of said access apertures; and
(c) an outlet stem connected at a proximal end thereof with said housing and being configured at the distal end thereof to receive the proximal end of the catheter, said outlet stem comprising:

(i) a plurality of prongs connected at a proximal end of each thereof to said housing, one of said prongs corresponding to each of said fluid cavities, said prongs projecting in a spaced-apart substantially parallel array from said housing and said prongs having distal ends positioned to be receivable individually in a corresponding one of each of the lumens of the catheters;
(ii) a plurality of exit passageways, one of said exit passageways corresponding to and communicating with an individual one of each of said fluid cavities; and
(iii) a plurality of stem channels extending within each of said plurality of prongs from said distal to said proximal ends thereof, and each of said plurality of stem channels communicating with one of said plurality of exit passageways.

34. An access port as recited in claim 33, wherein each of said stem channels is longitudinally formed through a separately configures one of said plurality of prongs, said plurality of prongs being spaced apart from each other by an elongate slot extending from the distal end of said outlet stem to a point intermediate the length of said outlet stem, the distal ends of said plurality of prongs each being configures so as to snugly accept a lumen of the catheter, with each lumen of the catheter communicating with a respective stem channel, and with the web of the catheter that separates the lumens thereof being received into the elongate slot between said plurality of said outlet stem.

35. An access port as recited in claim 33 or 34, wherein each of said plurality of prongs comprises a barb protruding radially outwardly from an outer surface thereof.

36. An access port as recited in claim 33 or 34, wherein the cross-section of each of said plurality of prongs corresponds to the internal cross-section of a corresponding lumen of the catheter.

37. An access port as recited in claim 33 or 34, wherein each of said plurality of prongs has a generally triangular cross-section.

38. An access port as recited in claim 33 or 34, wherein each of said plurality of prongs has a cross-section in the shape of a wedge of a circle.

39. An implantable access port system capable of being implanted beneath the skin of a patient, the access port system enabling repeated, non-destructive fluid communication between a needle piercing the skin of the patient and the proximal end of a selected one of the lumens of a multi-lumen catheter, said access port comprising:

(a) a needle-impenetrable housing enclosing a plurality of fluid cavities, said housing defining for each of said fluid cavities an individual access aperture communicating through said housing with each of said fluid cavities;
(b) a plurality of needle-penetrable septums, each of said septums being captured by said housing in and sealing an individual one of said access apertures; and
(c) an outlet stem connected at a proximal end thereof with said housing and being configured at the distal end thereof to receive the proximal end of the catheter and having a ramped portion formed intermediate said proximal and said distal ends, said outlet stem comprising:

(i) a plurality of prongs connected at a proximal end of each thereof to said housing, one of said prongs corresponding to each of said fluid cavities, said prongs projective in a spaced-apart substantially parallel array from said housing and said prongs having distal ends positioned to be receivable individually in a corresponding one of each of the lumens of the catheters; and
(ii) a plurality of exit passageways, one of said exit passageways corresponding to and communicating with an individual one of each of said fluid cavities, each of said exit passageways communicating with a stem channel extending within an individual one of said prongs from said distal to said proximal ends thereof;

(d) a dual-lumen catheter capable of being attached at the proximal end thereof to said outlet stem by advancement over the outside of said outlet stem; and
(e) a locking sleeve capable of being slid over said catheter to exert radial compression upon said catheter and said outlet stem to resist the removal of said catheter from said outlet stem.

40. An implantable access port system as recited in claim 39, wherein each of said plurality of prongs comprises barbs protruding radially outwardly from an outer surface thereof.

41. An implantable access system as recited in claim 39 or 40, wherein said locking sleeve comprises safety means for biasing the locking sleeve into a locking position thereof on the outside of said catheter when said proximal end of said catheter is received on said outlet stem.

42. An implantable access port system as recited in claim 41, wherein said safety means comprises:

(a) an internal ramp protruding inwardly from an inner surface of said locking sleeve to cooperatively engage said ramped portion of said outlet stem when said locking sleeve is in said locked position; and
(b) a gradually tapering surface, said tapering suffice having a larger diameter at the distal end of said locking sleeve and tapering gradually inwardly to a point intermediate said distal and said proximal ends of said locking sleeve, said gradually tapering region requiring energy to be applied to said sleeve to remove said sleeve from said locked position thereof from said catheter.

43. An access port system as recited in any one of claims 39 to 42, wherein said locking sleeve is configured so as to compress the wall of the catheter against the outer surface of said outlet stem at a position intermediate thereupon and to urge said plurality of prongs of said outlet stem toward each other into engagement with the web separating the lumens of the catheter, thus locking the catheter to the stem.

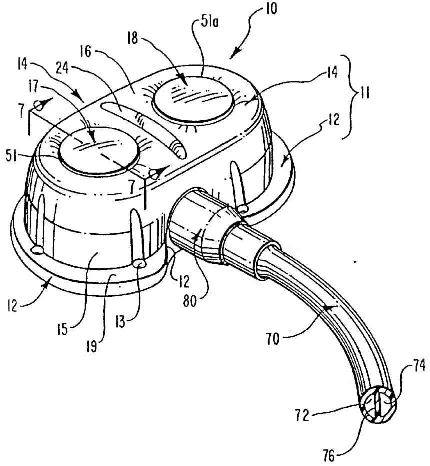

FIG. 1

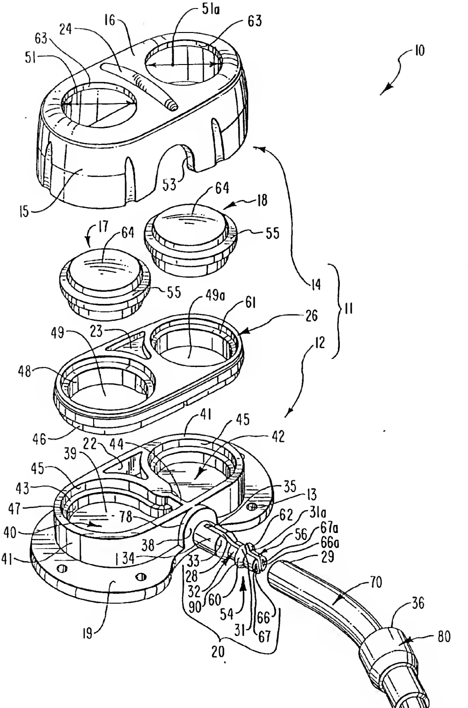
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FIG. 2

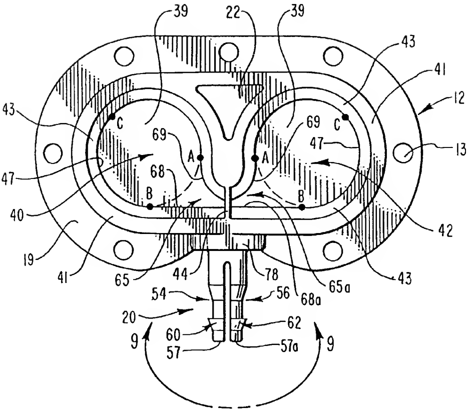
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FIG. 3

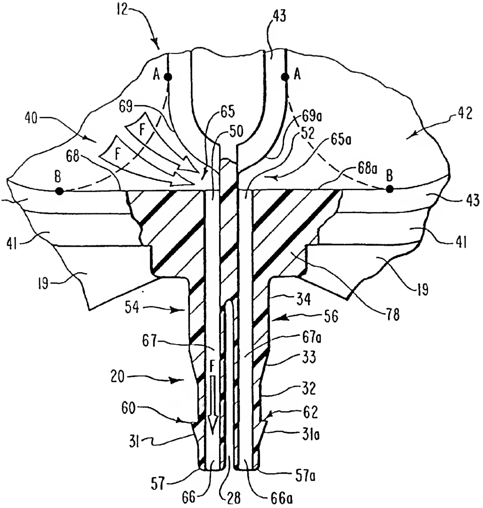

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FIG. 4

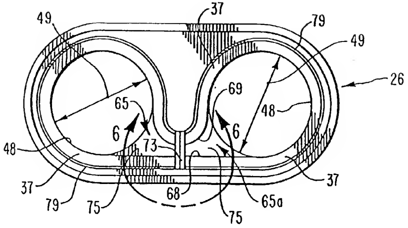

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FIG. 5

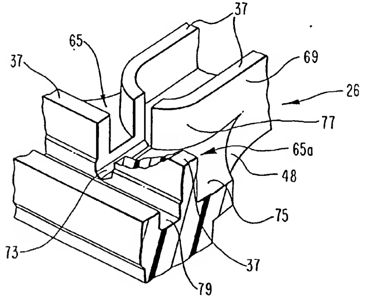

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FIG. 6

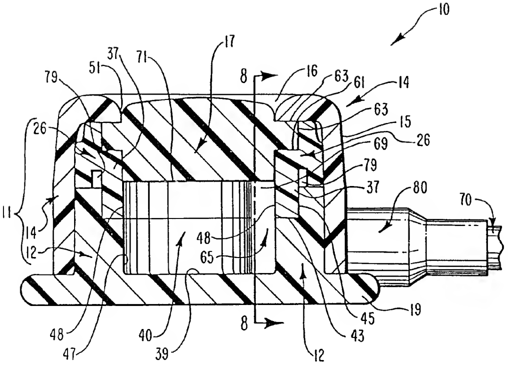
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FIG. 7

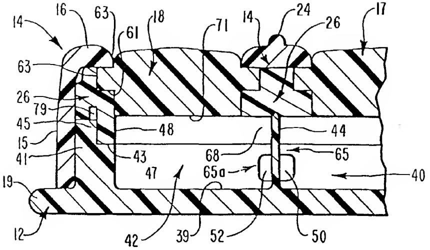
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FIG. 8

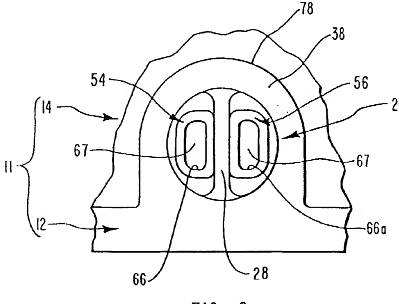
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FIG. 9

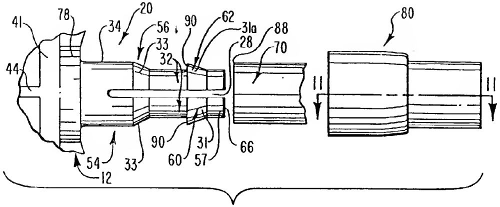
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FIG. 10

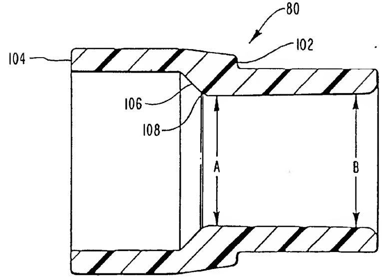
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FIG. 11

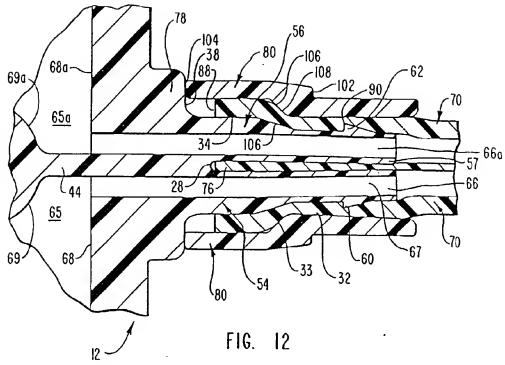
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FIG. 12

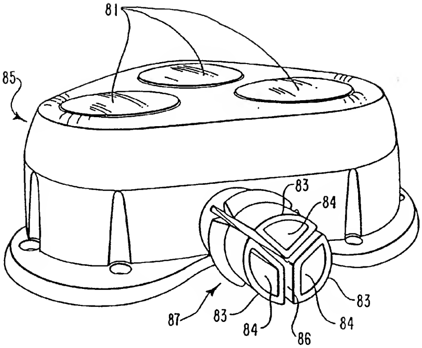

FIG. 13

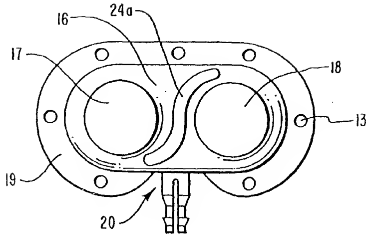

FIG. 14

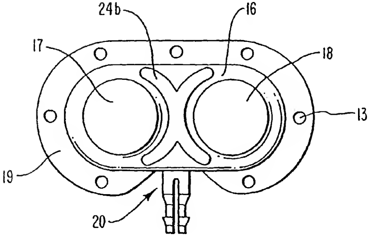

FIG. 15

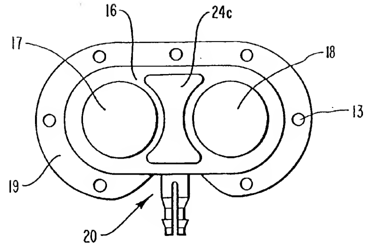

FIG. 16

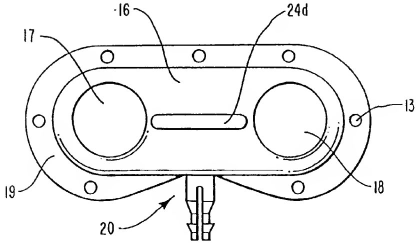

FIG. 17

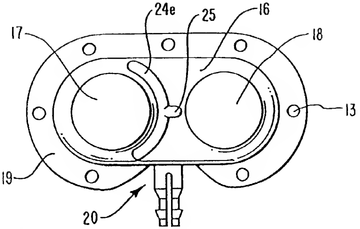

FIG. 18

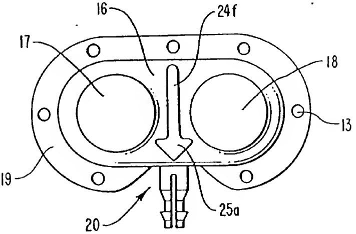

FIG. 19